Letters of Opposition for SB32

1. Academy of Managed Care Pharmacy (AMCP)
2. Alaska Rheumatology Alliance – Dr. Botson
3. Board of Pharmacy (BOP)
4. Nancy Merriman Comments

AMCP | Academy of Managed Care Pharmacy®

February 27, 2017

The Honorable Mia Costello, Chair
Senate Labor and Commerce Committee
State Capitol Room 504
Juneau, Alaska, 99801

RE: Senate Bill No. 32 – Biological Product Substitutions

Dear Senator Costello:

The Academy of Managed Care Pharmacy (AMCP) is writing to express concerns with specific provisions of Senate Bill No. 32 regarding the regulation of biological products and the substitution of interchangeable biological products when dispensed by pharmacists. We strongly support the Biologics Competition and Innovation Act (BPCIA) definition of "interchangeable biologic product" which allows a pharmacist to substitute an interchangeable biologic product without the intervention of the health care provider who prescribed the "reference product". Senate Bill No. 32 includes an amendment to AS. 08.80.295 which allows the pharmacist to substitute an interchangeable biological product with the consent of the patient, we support that amendment because it is consistent with the BPCIA and Alaska law.

However, we oppose the additional administrative requirements in Senate Bill No. 32 to dispense an interchangeable biological product that differ from existing requirements in Alaska for all other classes of FDA approved medications. We are also concerned about enacting additional requirements prior to the Food and Drug Administration (FDA) finalizing guidance on interchangeable biological products.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners, including members in Alaska, manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

Additional administrative burdens on pharmacists

The language proposed to amend AS 08.80.295 in sections (c) and (f), is problematic because it requires additional notification by the pharmacist to the prescriber and additional record keeping not required for any other class or category of drugs approved by the FDA. These provisions are unduly burdensome and time consuming for pharmacists and there are no proposed amendments that require the prescriber to maintain a record of the required notifications. Although the proposed amendments provide that notification can take place via the use of electronic systems, the primary mode of communication between prescribers and pharmacists is not via an electronic system. These provisions are not consistent with the intent of the BPCIA, which was to create an

abbreviated pathway for approval of these products by balancing innovation and consumer interests. These provisions create barriers to substitution by adding requirements for dispensing, and we cannot support them.

FDA guidance not yet final on interchangeable biological products

To date, the FDA has not finalized guidance on the determination of interchangeability. In fact, the FDA released a draft guidance on January 17 titled "Considerations in Demonstrating Interchangeability With a Reference Product" and the comment period closes on March 20, 2017. The FDA will not accept an application for approval of an interchangeable biological product until the guidance document is final.

The FDA Purple Book: Designated List of Biological Products

The FDA has already created a publically available reference document: The Purple Book: Lists of Licensed Biological Products (Purple Book) with reference product exclusivity and biosimilarity or interchangeability evaluations. When the draft guidance on interchangeability is finalized, the FDA will begin accepting applications and information will be available on licensed products in the Purple Book. Therefore, we recommend that the language proposed to amend AS 08.80.480 (38)(A) should include the title of the reference, i.e., the "Purple Book".

The reference in AS 08.80.480 (38)(B) to the "Approved Drug Products with therapeutic equivalence evaluations" which is commonly referred to as the FDA Orange Book, should be deleted. The Orange Book is the FDA's list of drug products approved under the Food, Drug and Cosmetic Act. As previously mentioned applications for and approval of interchangeable biological products are only authorized under the BPCIA and will be listed only in the Purple Book.

In conclusion, we urge you to adopt the language that updates Alaska statutes to allow for the substitution of biologic products with FDA approved interchangeable biological products and to provide the liability protections for pharmacists dispensing those products. However, we urge you delete the additional administrative requirements not required for any other class of FDA approved drugs and the paragraph that references the Orange Book. Lastly, AMCP also encourages the legislature to review the final FDA guidance and at that time determine whether additional legislation is necessary. If you have any questions about our position, please contact AMCP's Director of Legislative Affairs, Reginia Benjamin, at (703) 683-8416 or rbenjamin@amcp.org.

Sincerely,

Susan A. Cantrell, RPh, CAE
Chief Executive Officer

Alaska Rheumatology Alliance
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February 8, 2017

RE: Senate Bill 32 Opposition

Dear Senator Wilson:

On behalf of the Alaska Rheumatology Alliance, I would like to thank you for taking the time to receive our concerns regarding the newly proposed legislation, Senate Bill 32. As you recall this is the legislation updating pharmacy substitution laws for prescription medications, specifically biological products and substitutability of FDA approved "interchangeable" products.

The concept of the legislation is to define previously undefined biological products (both currently available and future products), establish a way to identify equivalent, interchangeable products, and provide a mechanism for substitution of a prescribed medication at the pharmacy level. The legislation would also mandate communication between the prescribing practitioner and the dispensing pharmacy to document the medication actually provided in the case of a substitution. Though this is a state initiative, there has been significant pressure nationally to accomplish this across the country.

Senate Bill 32, as outlined for Alaska, would define the biologic products, use the FDA approved "interchangeable list", and allow a pharmacy to substitute a biologic medication without prescriber input, only requiring notification to the prescriber within 3 business days of dispensing the medication to the patient.

The Alaska Rheumatology Alliance strongly opposes the proposed Senate Bill 32 as it is currently written, specifically based on the unrestricted substitution allowance and the 3 days reporting requirement.

Rheumatology as a specialty uses a number of biologic medications to the benefit of our patients and will likely continue to have new agents available in the future. Biologic medications are typically last line agents. They are very specific and often a patient has taken years of unsuccessful treatments to find a medication that works for them. The right medication; however, can be life changing. The medications are also, understandably, very costly and we are sensitive to this in the medications we prescribe. Multiple factors, including patient co-morbidities, other concomitant medications, route of administration, cost, and other factors are taken in to consideration when selecting the right biologic medication.

When there is an unrestricted ability to switch a biologic medication, the patient is placed at a significant risk. As each patient is an individual, some patients will not respond as well to an alternative medication and this is a large concern. Also the practitioner-patient relationship is undermined in this situation. Furthermore with a 3 days post-dispensing reporting requirement, in most cases the medication will

already be administered before the knowledge of the switch becomes known to the provider and the ability to have an informed discussion with the patient is lost.

The Alaska Rheumatology Alliance is in support of cost saving measures for patients and in some cases an interchangeable product could be appropriate, but the determination needs to be made prior to the substitution. Therefore, the Alaska Rheumatology Alliance would be in support of a bill only if notification and authorization was done PRIOR to the dispensing of the interchangeable product. This open communication would be in the best interest of patient and not undermine our work as practitioners.

As a registered pharmacist and actively practicing rheumatologist who uses a significant number of biologic medications, I have been able to reflect on the impact of this proposed change and feel strongly about this legislation.

We have heard the argument for using the “Dispense As Written” or “DAW” code as a way to prevent substitution. While this would definitely stop the interchange of medication, from our perspective as physicians, the “Dispense As Written” code is a nonnegotiable order. At times this is appropriate, but often there are times when a "brand name product" would be preferred but not necessary. Having the legislation with pre-notification and authorization allows the pharmacist an open dialogue with regards to medication with the provider. In many instances, the physician will not have an opposition with the substitution, especially when given additional information, such as cost savings to the patient, which the pharmacist would be able to communicate immediately based on other factors such as insurance preferences and availability of the product.

Previously I worked as a pharmacist and know that the submissions to insurance from the pharmacy is a real time process. It is immediately known whether there would be a cost savings with using a "generic" (or in this case an interchangeable product). This is the valuable information that could be communicated to the provider and then make the best choice for the patient.

I also know that pharmacies are able to electronically submit refill request and notifications of "prior authorizations needed" insurance rejections immediately on a real-time basis to the prescribing provider. There is no reason that this could not be applied to interchangeable product substitutions.

I have personally been involved for months at the national level regarding the impact of such legislation and have worked closely with the Arthritis Foundation, Coalition of State Rheumatology Organizations, and with the American College of Rheumatology. Locally the Alaska Rheumatology Alliance has been working with the community rheumatologists and those at the Alaska Native Hospital. I have also provided feedback and attended a December 13th, meeting in Anchorage which was an informational discussion attended by Dermatologists, Rheumatologists, Pharmacists, Industry representatives, and political activists. I am quite confident that the concerns outlined above echo those of the professionals and practitioners in the community.

The legislation has been touted by its initiators as a way to provide better access to expensive medications and reduce overall pharmacy and healthcare costs while providing accountability and

tracking of the medications. This pressure is spearheaded by pharmaceutical companies, with no doubt, financial incentives in place. While this concept of cost saving to the medical system is a noble one, in other states this has not thus far come to fruition.

Each state has the ability to adopt its own legislation based on its own needs. Alaska has a unique set of challenges because of the remote nature of some pharmacies and clinics, the lack of standard electronic medical records, and the heterogeneity of the population we treat as practitioners. Alaska needs to take the lead in the country in caring for our own patients. What might work for other states is unlikely to work in Alaska and our legislation needs to reflect this difference.

This bill has the support of a number of National Organizations. These same organizations have supported bills in other states. What the initiators of this bill have failed to establish is the support of local Alaskan providers of medical care.

As a take away point, Alaska Rheumatology Alliance would support a bill with a change in language as follows:

22 * Sec. 5. AS 08.80.295 is amended by adding new subsections to read:

23 (c) Except as provided in (d) of this section, if an interchangeable biological

24 product exists for a biological product prescribed to a patient, the dispensing

25 pharmacist or the pharmacist's designee shall communicate to the prescribing

26 practitioner information regarding the **proposed** biological product **that would be** provided to the patient,

27 including the name and manufacturer of the biological product. The communication **must be provided and authorization from the prescribing practitioner**

28 must be **obtained** ~~provided within three business days after dispensing the biological product~~ **prior to dispensing the interchangeable biological product. The communication may be provided** as

29 follows:

Thank you for your attention to this matter and the discussion points above. Please do not hesitate to contact me with any additional questions or concerns.

Sincerely,

John Botson, MD, RPh

President, Alaska Rheumatology Alliance

THE STATE of ALASKA
GOVERNOR BILL WALKER

Department of Commerce, Community, and Economic Development

BOARD OF PHARMACY
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March 6, 2017

The Honorable Senator Hughes
Alaska Senate
Alaska State Capitol
Juneau, AK 99801

RE: SB 32: An Act relating to biologic products

The Alaska Board of Pharmacy at its March meeting via teleconference, voted unanimously in opposition to the current language in Senate Bill 32 (An act relating to biological products, the practice of pharmacy, and providing for an effective date). The Board feels that the current bill, in particular, section 5 and the reporting requirements, does not follow the intent of the BPCI Act of 2009 with relation to interchangeable biosimilars and its purpose of increasing access to expensive medications for patients in need. The BPCI Act allows for the substitution of "interchangeable" biosimilars, of which have been deemed so by the FDA, without the intervention of the prescribing practitioner.

What is important to note is the "interchangeable" biosimilar vs. the biosimilar. A biosimilar product is a biological product that is highly similar to a biological "reference" product in that it has the same mechanism of action, route of administration, dosage form, and strength. However, a biosimilar has not met the safety standards determined for "interchangeability" by the FDA. Once these standards have been met, it is deemed safe and effect by the FDA and treated as any other generic product on the market and may be substituted at the patient and pharmacist's discretion without intervention by the prescribing practitioner as stated so in the BPCI Act of 2009.

To Note, it was stated by then FDA Commissioner Margaret A. Hamburg, MD, in 2015, "Patients and the health care community can be confident that biosimilar products approved by the FDA meet the agency's rigorous safety, efficacy and quality standards." This is the same confidence we are to have in any and all generic equivalent products that we as pharmacists are currently allowed to substitute for without notification to the prescriber. We feel that this notification serves as an unintended barrier to access of these medications. It is also worth noting that there are no currently available "interchangeable" biosimilar medications on the market and pushing legislation through that has potentially harmful consequences with regards to access of the medications, for the sake of having legislation in place is not advisable. It is the Boards position that we do see the need for legislation regarding biosimilars but want the legislation to follow the BPCI Act of 2009 and its intent of increasing access to medications for those in need.

Sincerely,
Leif J. Holm, PharmD
Chair, Alaska Board of Pharmacy

p.p.
Donna Bellino
Licensing Examiner

Db:lh

Nancy Merriman
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February 9, 2017

Senator David Wilson
Chair, Senate Health & Social Services Committee
State Capitol Room 115
Juneau AK, 99801

Senator Natasha von Imhof
Vice Chair, Senate Health & Social Services Committee
State Capitol Room 514
Juneau AK 99801

Re: Testimony, SB 32. Senate Health & Social Services Committee

Dear Chair Wilson and Vice Chair von Imhof,

I am writing to provide constructive comment on Senate Bill 32, "An act relating to biological products; relating to the practice of pharmacy; relating to the Board of Pharmacy; and providing for an effective date".

Thank you for the opportunity to provide comments on Senate Bill 32. I am one of the patients who would be directly and negatively affected by the implementation of this bill, should it be passed as written.

I have an array of chronic auto-immune conditions that are treated with biologic medications. I have tried four different brand-name biologic drugs – given by injection or infusion – over the course of fifteen years. I have developed life-threatening allergic reactions to some; others interact adversely with other medications I take; some are simply ineffective. I have landed on one which is working adequately – for now.

SB 32, as written, would allow the pharmacist – not my physician – to decide to substitute a "biosimilar" drug for the band-name biologic. And only requires that the pharmacist notify my physician up to three days after the substitute dispensing is done. This is unacceptable. This practice would put me in harm's way – and be counter to my physician's directive, which has been shaped and tested over 15 years of dealing with my co-morbidities.

I understand that the pharmacist has to notify the patient of the substitution, but if a less-well-informed patient is presented with the option, they could understand it in the same as getting a generic drug instead of name brand. And, that, in the case of biologics, is simply not true. Biologics are proteins generated from living organisms, and biosimilars are not "bio-same". They are <u>different</u>.

Language could be changed in this bill to make it safer for patients and more respectful of the doctor-patient relationship, as follows (added/changed language is bolded):

> * Sec. 5. AS 08.80.295 is amended by adding new subsections to read: (c) Except as provided in (d) of this section, if an interchangeable biological product exists for a biological product prescribed to a patient, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner information regarding the **proposed** biological product **that would be** provided to the patient, including the name and manufacturer of the biological product. The communication **must be provided and authorization obtained from the prescribing practitioner** ~~**must be provided within three business days after dispensing the biological product**~~ **prior to dispensing the interchangeable biological product. The communication may be provided** as follows:

I appreciate your consideration of these comments, and invite you to contact me for further information or clarification.

Sincere regards,

Nancy Merriman
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